PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Avner Gal *et al*

Assignee: Integrity Applications Ltd.

Title: A METHOD OF MONITORING GLUCOSE LEVEL

Filed: Concurrently herewith

Attorneys' Docket: 605/1

INFORMATION DISCLOSURE STATEMENT

SIR:

Pursuant to provisions of 37 C.F.R. 1.97 and 1.98, Applicant hereby identifies the U.S. Patents and Publications of which it has knowledge. Applicant makes no representation as to whether or not it has conducted a search and is identifying and disclosing these patents and publications in order to comply with its duty to disclose, pursuant to 37 C.F.R. 1.56. Copies of these patents and publications are enclosed, along with PTO form 1449.

Further, the filing of this Information Disclosure Statement does not constitute an admission that the patents are prior art, or are material to patentability of the subject matter of this invention.

Inventor	Pat. No.	Date
Thomas	5,119,819	Jun 9, 1992
Gozani	5,771,891	Jun 30, 1998
Cho	5,795,305	Aug 18, 1998
Cho	5,924,996	Jul 20, 1999
Chou	5,941,821	Aug 24, 1999
Chou	6,049,728	Apr 11, 2000
Matsumura	5,050,612	Sep 24, 1991
Rosencwaig	5,657,754	Aug 19, 1997
Buchert	5,666,956	Sep 16, 1997
Gozani	5,752,512	May 19, 1998
Fuller	5,792,668	Aug 11, 1998
Pinsky	6,150,812	Nov 21, 2000
Eppstein	6,226,541	May 1, 2001
Oraevsky	6,309,352	Oct 30, 2001
Bauer	6,322,963	Nov 27, 2001
Bauer	6,342,347	Jan 29, 2002
Chaiken	6,377,828	Apr 23, 2002
Oraevsky	6,405,069	Jun 11, 2002

Thomas teaches a method of monitoring blood glucose, but it is based on only an acoustic velocity measurement based on the two-way travel time of an ultrasound pulse. This is actually an invasive process, as the sensor enters the body through the ear lobe.

Gozani ('891) discloses a non-invasive method for blood analyte measurement. First, there is electrical stimulation of an endogenous tissue and then the detection of the resulting electrical response to the stimulus. One embodiment shows electrical stimulation of a hypoxic peripheral nerve, and then the detection of the resulting Compound Action Potential elsewhere along the nerve.

Cho ('305 and '996) uses combined temperature and measurements of either infrared radiation or thermal conductivity to determine the glucose concentration.

Chou ('821 and '728) determines the blood glucose by a photoacoustic measurement in which the acoustic pulse is generated by heating the patient's skin with electromagnetic radiation.

Matsumura is directed towards a temperature sensor.

Rosencwaig is directed towards an apparatus that includes "means for selectively inducing a periodic heating at a predetermined frequency ... in a manner to create thermal waves".

Buchert measures glucose level by detecting the infrared radiation naturally emitted by a human body.

Gozani ('512) is a blood analyte concentration monitor, which applies a stimulus to an endogenous tissue.

Fuller determines the concentration of a target chemical by subjecting the specimen to radio frequency electromagnetic components. It teaches in-vivo noninvasive assays of NaCl and glucose in blood based on electromagnetic impedance measurements.

Pinsky detects chemical reactions by utilizing a magnetometer probe to detect a change in the electromagnetic field strength. This is an invasive measurement of blood glucose

Eppstein is directed towards a calibration device for a diagnostic medical instrument whose measurements are based on transmitting electromagnetic or acoustic waves and receiving the reflected waves.

Oraevsky ('352) monitors tissue properties in real time during treatment by using an optoacoustic imaging system.

Bauer ('963 and '347) discloses invasive measurements of blood glucose. This is done in the '963 patent by measurement of changes in induced electromotive force, current or other electrical properties during analyte exposure to the sensor. In the '347 patent the sensor makes use of changes in electrostatic fields associated with macromolecular binding agents during their interaction with analytes.

Chaiken measures an analyte in a tissue of a subject. It involves contacting the tissue with electromagnetic radiation.

Oraevsky ('069) measures glucose by determining laser-induced profiles of absorbed optical energy distribution in issues via measurements of spatial profile of optically-induced acoustic (pressure) transients using an optoacoustic transducer

Applicant's unique invention is a method of monitoring or measuring the concentration of glucose level in human and animal blood using a non-invasive technique, which includes measurements of the speed of sound through the blood, while inside the body, the conductivity of the blood, by means of electromagnetic inductance, and the heat capacity of the blood, by means of changing the temperature of the measured volume. The instant invention uses measurements of three distinct parameters to determine the blood glucose level, thereby substantially increasing the accuracy of the measurement. None of the prior art techniques disclose any non-invasive method of calculating blood glucose by measuring three separate and distinct blood parameters. Further, none of the prior art methods utilize any measurement of electrical conductivity and heat capacity, which are two of the parameters measured in the instant invention.

Therefore, the instant invention is patentably distinct from, and unobvious in view of, the above patents, whether considered singly or in combination.

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Respectfully submitted
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 1

Compl te if Kn wn	
Application Number	
Filing Date	
First Named Inventor	Avner GAL
Art Unit	
Examiner Name	
Attorney Docket Number	605/1

U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Document Number Number-Kind Code[2] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		US- 5119819	6/9/92	Thomas	
		US- 5771891	6/30/98	Gozani	
		US- 5795305	8/18/98	Cho	
		US- 5924996	7/20/99	Cho	
		US- 5941821	8/24/99	Chou	
		US- 6049728	4/11/00	Chou	
		US- 5050612	9/24/91	Matsumura	
		US- 5657754	8/19/97	Rosencwaig	
		US- 5666956	9/16/97	Buchert	
		US- 5752512	5/19/98	Gozani	
		US- 5792668	8/11/98	Fuller	
		US- 6150812	11/21/00	Pinsky	
		US- 6226541	5/1/01	Eppstein	
		US- 6309352	10/30/01	Oraevsky	
		US- 6322963	11/27/01	Bauer	
		US- 6342347	1/29/02	Bauer	
		US- 6377828	4/23/02	Chaiken	
		US- 6405069	6/11/02	Oraevsky	
		US-			

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.[1]	Foreign Patent Document Country Code[3]-Number[4]-Kind Code[5] (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T[6]

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. [1] Applicant's unique citation designation number (optional). [2] See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. [3] Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). [4] For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. [5] Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. [6] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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